

03-27-06

TFW 3737



PATENTS
CUSTOMER NO. 29052
ATTY. DOCKET NO. 23578-0010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Continuation Reissue Application of:)	
)	
Uber, III et al.)	
)	Art Unit: 3737
Serial No.: 09/545,582)	
)	Examiner: R. Smith
Filed: April 7, 2000)	
)	
For: Patient Infusion System for Use)	
With MRI)	

**PETITION TO EXPUNGE UNDER 37 CFR 1.59(b) FOR INFORMATION
UNINTENTIONALLY SUBMITTED IN APPLICATION**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR §1.59(b) and M.P.E.P. §724.05 (II), Applicants hereby Petition to Expunge certain information that was unintentionally and inadvertently included in the Fifth Supplemental Information Disclosure Statement (IDS) as Exhibits 17-30 to Reference Cite No. Z on PTO-1449 form as submitted to the US Patent and Trademark Office on January 24, 2006 in the above-identified application. The Commissioner is hereby authorized to charge the \$200.00 petition fee under 37 CFR §1.17(g), or any other fees due, to Deposit Account No. 19-5029 (Ref.: 23578-0010).

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Express Mail Label No. EL 973738882 US Date: March 24, 2006

REMARKS

M.P.E.P. §724.05 (II) addresses Information Unintentionally Submitted in Application. It states that a petition to expunge information unintentionally submitted in an application (other than information forming part of the original disclosure) may be filed under 37 CFR 1.59(b), provided that:

- (A) the Office can effect such return prior to the issuance of any patent on the application in issue;
- (B) it is stated that the information submitted was unintentionally submitted and the failure to obtain its return would cause irreparable harm to the party who submitted the information or to the party in interest on whose behalf the information was submitted;
- (C) the information has not otherwise been made public;
- (D) there is a commitment on the part of the petitioner to retain such information for the period of any patent with regard to which such information is submitted;
- (E) it is established to the satisfaction of the Director that the information to be returned is not material information under 37 CFR 1.56; and
- (F) the petition fee as set forth in 37 CFR 1.17(*>g<) is included.

Accordingly, Applicants hereby respectfully submit this Petition to Expunge Exhibits 17-30 from Reference Cite No. Z on form PTO-1449 of the Fifth Supplemental IDS entitled "Medrad's Opposition to Defendants' Memorandum for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE 37,602 Under 35 U.S.C. §103, submitted on 05/27/05 (Filed Under Seal)," that were unintentionally and inadvertently submitted. Applicants respectfully request that the Office returns and expunges Exhibits 17-30 from Reference Cite No.

Z prior to the issuance of any patent on the present application, because the claims of the application are still pending and subject to Examiner's further examination and determination of patentability.

Furthermore, Applicants respectfully state that the information disclosed in these Exhibits 17-30 is not material information under 37 CFR §1.56 such that Applicants have a duty to disclose the information to the Patent Office. As discussed in Applicants' Third Supplemental Amendment filed January 24, 2006, there are now three independent claims remaining (Claims 54, 118 and 124) and a total of seventeen claims pending. Claims 54-56, 59, and 62 were amended to claim *inter alia* those certain embodiments wherein the injector control unit includes a drive motor connected to the injector by a non-rigid drive connection, and wherein the communication control link is substantially non-reactive with the magnetic resonance imaging system during operation. Newly added claims 118-123 claim *inter alia* a combined two syringe embodiment with two drive motors, and a control link substantially non-reactive with the magnetic resonance imaging system during operation. Newly added claims 124-128 claim *inter alia* an embodiment with two drive motors and a control link substantially non-reactive with the magnetic resonance imaging system during operation.

None of the Exhibits 17-30 provides information material to patentability of the claimed features as stated above. Rather, Exhibits 17-30 were used by Applicants in partial response to motions filed in the litigation of a related patent (the '602 reissue patent) and expert reports to argue that the inventions claimed therein were not obvious in light of objective indicia of non-obviousness. As a general matter, objective indicia of non-obviousness can also be filed, if an applicant so chooses, to refute a prima facie rejection for obviousness under 35 U.S.C. §103(a).

In the present case, the information relating to objective indicia of non-obviousness of the claims in the '602 reissue patent is not material to patentability of the present claims. Applicants note that no prima facie showing of obviousness has been established by the Examiner for the pending claims, and applicants did not submit these documents to the Patent Office to address such a showing. Rather, applicants inadvertently submitted these documents along with other items filed to provide the Patent Office information from the litigation involving the '602 reissue patent. Since these particular documents are not material and were inadvertently provided, applicants respectfully submit that they may be expunged from the record.

Applicants further state that the Exhibits 17-30 were not intended to be submitted to the Patent Office because they include certain information that was designated confidential by the parties in litigation involving the '602 reissue patent and has not been made public. Applicants, as one of the parties, obtained this information during the ordinary course of litigation, and is under an obligation to maintain the confidentiality of the information. Furthermore, the failure to return and expunge the information from the record would cause irreparable harm because of the confidential nature of the information disclosed in Exhibits 17-30 claimed by Applicants' opponent in the litigation. In particular, Applicants' opponent in the litigation has requested that the present Petition to Expunge be made.

Exhibit 17 includes several exhibits from a deposition, including interoffice memoranda, correspondence, presentations, drawings, meeting minutes and project proposals, which generally disclose efforts relating to development of MR injectors by others – applicants submit that these materials do not represent prior art to the present application. Nothing in Exhibit 17 teaches or suggests an embodiment where the injector control unit is inside the shielded room

and includes a drive motor connected to the injector by a non-rigid drive connection and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Nor does this Exhibit teach or suggest an embodiment with two syringe drive mechanisms and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Therefore, the items in the Exhibit are not material to patentability and should be expunged.

Exhibit 18 is the transcript from the deposition to which the items identified in Exhibit 17 above were used as exhibits. The deposition transcript generally discloses efforts relating to development of MR injectors by others – applicants submit that these materials do not represent prior art to the present application. Exhibit 18 does not teach or suggest an embodiment where the injector control unit is inside the shielded room and includes a drive motor connected to the injector by a non-rigid drive connection and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Nor does this Exhibit teach or suggest an embodiment with two syringe drive mechanisms and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Therefore, the Exhibit is not material to patentability and should be expunged.

Exhibit 19 is a June 29, 1994 memorandum entitled “MR Investigation” which generally discloses the characteristics of MRI systems and the notion of designing an injector to be used with MR imaging. Exhibit 19 does not teach or suggest an embodiment where the injector control unit is inside the shielded room and includes a drive motor connected to the injector by a non-rigid drive connection and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Nor does this Exhibit teach or suggest an embodiment with two syringe drive mechanisms and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Therefore, the Exhibit is not material to patentability and should be expunged.

Exhibit 20 includes a series of interoffice memoranda and meeting minutes which generally disclose efforts relating to development of MR injectors by others – applicants submit that these materials do not represent prior art to the present application. Exhibit 20 also includes the same June 29, 1994 memorandum identified in Exhibit 19 above. Nothing in Exhibit 20 teaches or suggests an embodiment where the injector control unit is inside the shielded room and includes a drive motor connected to the injector by a non-rigid drive connection and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Nor does this Exhibit teach or suggest an embodiment with two syringe drive mechanisms and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially

non-reactive with the magnetic resonance imaging system during operation. Therefore, the items in the Exhibit are not material to patentability and should be expunged.

Exhibit 21 includes a series of correspondence which generally disclose efforts relating to development of MR injectors by others – applicants submit that these materials do not represent prior art to the present application. Nothing in Exhibit 21 teaches or suggests an embodiment where the injector control unit is inside the shielded room and includes a drive motor connected to the injector by a non-rigid drive connection and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Nor does this Exhibit teach or suggest an embodiment with two syringe drive mechanisms and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Therefore, the items in the Exhibit are not material to patentability and should be expunged.

Exhibit 22 is a November 21, 1994 project authorization proposal which generally discloses the broad concept of developing an MR injector. Exhibit 22 does not teach or suggest an embodiment where the injector control unit is inside the shielded room and includes a drive motor connected to the injector by a non-rigid drive connection and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Nor does this Exhibit teach or suggest an embodiment with two syringe drive mechanisms and a communication control link that extends between the system controller

outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Therefore, the Exhibit is not material to patentability and should be expunged.

Exhibit 23 is a facsimile and cover sheet dated November 11, 1994 which generally discloses responses to a questionnaire seeking clinical information regarding MRI procedures in general, including the use of injection procedures with MR imaging. Exhibit 23 does not teach or suggest an embodiment where the injector control unit is inside the shielded room and includes a drive motor connected to the injector by a non-rigid drive connection and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Nor does this Exhibit teach or suggest an embodiment with two syringe drive mechanisms and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Therefore, the Exhibit is not material to patentability and should be expunged.

Exhibit 24 is a March 22, 1995 draft of a document entitled "Investigational Plan: MR Injector" which generally discloses a procedure for clinically testing the safety and efficacy of an injector to be used with MR imaging. Exhibit 24 does not teach or suggest an embodiment where the injector control unit is inside the shielded room and includes a drive motor connected to the injector by a non-rigid drive connection and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Nor

does this Exhibit teach or suggest an embodiment with two syringe drive mechanisms and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Therefore, the Exhibit is not material to patentability and should be expunged.

Exhibit 25 is a February 16, 1996 memorandum which generally discloses the details surrounding the 510(K) submission for an injector to be used with MR imaging. Exhibit 25 does not teach or suggest an embodiment where the injector control unit is inside the shielded room and includes a drive motor connected to the injector by a non-rigid drive connection and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Nor does this Exhibit teach or suggest an embodiment with two syringe drive mechanisms and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Therefore, the Exhibit is not material to patentability and should be expunged.

Exhibit 26 is a set of handwritten notes which generally discloses the requirements and specifications of an MR injector – applicants submit that these notes do not represent prior art to the present application. Exhibit 26 does not teach or suggest an embodiment where the injector control unit is inside the shielded room and includes a drive motor connected to the injector by a non-rigid drive connection and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-

reactive with the magnetic resonance imaging system during operation. Nor does this Exhibit teach or suggest an embodiment with two syringe drive mechanisms and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Therefore, the Exhibit is not material to patentability and should be expunged.

Exhibit 27 includes a document entitled “MRI Injector Specification” dated January 18, 1995 which generally discloses the specifications of an injector to be used with MR imaging. Exhibit 27 also includes a document entitled “MRI Injector Recommendation” dated August 26, 1994 which generally discloses a recommendation that development begin on an injector to be used with MR imaging. Exhibit 27 also includes a series of drawings dated November 1 and December 21, 1994 which generally disclose portions of an injector to be used with MR imaging. Nothing in Exhibit 27 teaches or suggests an embodiment where the injector control unit is inside the shielded room and includes a drive motor connected to the injector by a non-rigid drive connection and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Nor does this Exhibit teach or suggest an embodiment with two syringe drive mechanisms and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Therefore, the items in the Exhibit are not material to patentability and should be expunged.

Exhibit 28 is an interoffice memorandum entitled “MR Injector” dated March 18, 1994 which generally discloses costs associated with developing an MR injector. Exhibit 28 does not teach or suggest an embodiment where the injector control unit is inside the shielded room and includes a drive motor connected to the injector by a non-rigid drive connection and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Nor does this Exhibit teach or suggest an embodiment with two syringe drive mechanisms and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Therefore, the Exhibit is not material to patentability and should be expunged.

Exhibit 29 is a copy of an agenda for a March 25, 1994 meeting and accompanying documents which generally disclose costs associated with developing an MR injector. Exhibit 29 does not teach or suggest an embodiment where the injector control unit is inside the shielded room and includes a drive motor connected to the injector by a non-rigid drive connection and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Nor does this Exhibit teach or suggest an embodiment with two syringe drive mechanisms and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Therefore, the Exhibit is not material to patentability and should be expunged.

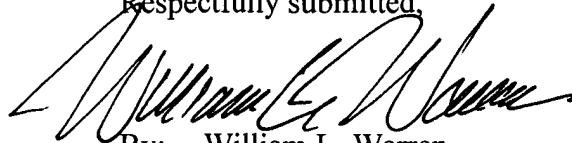
Exhibit 30 is the Expert Report of Dr. Allyn D. Strickland, submitted on February 14, 2005, which discloses Applicants' position on the amount of damages to which Applicants' are entitled. Exhibit 30 does not teach or suggest an embodiment where the injector control unit is inside the shielded room and includes a drive motor connected to the injector by a non-rigid drive connection and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Nor does this Exhibit teach or suggest an embodiment with two syringe drive mechanisms and a communication control link that extends between the system controller outside the shielded room and the injector control unit, and that is substantially non-reactive with the magnetic resonance imaging system during operation. Therefore, the Exhibit is not material to patentability and should be expunged.

Therefore, for the reasons stated above, Applicants hereby petition to expunge under 37 CFR §1.59(b) to return and expunge Exhibits 17-30 of Reference Cite No. Z that were unintentionally and inadvertently submitted with the Fifth Supplemental IDS in this application.

In re Continuation Reissue Application of
Uber, III et al.
09/545,582

The Commissioner is also hereby authorized to charge a petition fee of \$200.00 under 37 CFR §1.17(g), or any additional fees due, to Deposit Account No. 19-5029 (Ref. 23578-0010), and is encouraged to call the undersigned attorney at 404-853-8081 if any questions arise.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'William L. Warren', is written over the typed name.

By: William L. Warren
Reg. No. 36,714
Attorney for Applicants

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